

**APPLICATION
FOR
UNITED STATES PATENT**

TITLE OF INVENTION

TISSUE RETRACTOR AND DRILL GUIDE

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TISSUE RETRCTOR AND DRILL GUIDE

FIELD OF THE INVENTION

The present invention relates to devices for assisting in spinal surgery, and more particularly to a tissue retractor and drill guide for introducing spinal tools and devices.

5 BACKGROUND OF THE INVENTION

Advancing age, as well as injury, can lead to changes in the bones, discs, joints, and ligaments of the spine, producing pain from nerve root compression. Under certain circumstances, alleviation of pain can be provided by performing a spinal fusion. This is a procedure that involves joining two or more adjacent vertebrae with a bone fixation device so that they no longer are able to move relative to each other. For a number of known reasons, bone fixation devices are useful for promoting proper healing of injured or damaged vertebral bone segments caused by trauma, tumor growth, or degenerative disc disease. The external fixation devices immobilize the injured bone segments to ensure the proper growth of new osseous tissue between the damaged segments. These types of external bone fixation devices often include internal bracing and instrumentation to stabilize the spinal column to facilitate the efficient healing of the damaged area without deformity or instability, while minimizing any immobilization and post-operative care of the patient.

One such device is a bone fixation plate that is used to immobilize adjacent skeletal parts such as bones. Typically, the fixation plate is a rigid metal or polymeric plate positioned to span bones or bone segments that require immobilization with respect to one another. The plate is fastened to the respective bones, usually with bone screws, so that the plate remains in contact with the bones and fixes them in a desired position. Bone plates can be useful in providing the mechanical support necessary to keep vertebral bodies in proper position and bridge a weakened or diseased area such as when a disc, vertebral body or fragment has been removed.

Such plates have been used to immobilize a variety of bones, including vertebral bodies of the spine. These bone plate systems usually include a rigid bone plate having a plurality of screw openings. The openings are either holes or slots for screw placement. The bone plate is placed against the damaged vertebral bodies and bone screws are used to secure the bone plate to

the spine and optionally to a prosthetic implant or bone graft positioned between the adjacent vertebrae. Implantation of the plate, however, can be difficult. Each plate must be properly aligned with the vertebral bodies, and holes for receiving the bone screws must be drilled into the vertebrae at precise angles. It is often necessary to use the bone plate as a drill guide for drilling and tapping the bone in preparation for receiving the bone screws. Such a procedure can be difficult, however, as the surgeon is required to securely and rigidly hold the bone plate against the vertebrae, obtain proper alignment, drill, tap, and finally set the bone screws.

The procedure may be further complicated by the need to retract tissue from the surrounding area. Retraction has traditionally required additional tools and an extra step to pull tissue away from the working area prior to and during the procedure. The use of such additional tools can hinder access to the site and can require a surgeon or an assistant to perform multiple tasks simultaneously. A retractor which is left in place during the procedure can also cause stress to the surrounding tissue and may cause the patient additional discomfort and a prolonged recuperation.

Accordingly, there remains a need for an instrument that can be used to perform multiple tasks during spinal surgery.

SUMMARY OF THE INVENTION

The present invention generally provides a tissue retractor and guide device having an elongate member with a guide member formed on or mated to a distal portion thereof. At least one lumen extends through the guide member for receiving a tool. In use, the guide member is adapted to couple to a spinal implant, and the distal portion of the elongate member is effective to retract tissue disposed adjacent to the guide member.

The guide member can have a variety of configurations, but in an exemplary embodiment it includes two lumens extending therethrough and positioned at an angle with respect to each other. While the lumens can be formed in a housing having virtually any configuration, in an exemplary embodiment, the guide member includes a first barrel having a lumen extending therethrough, and a second barrel having a lumen extending therethrough. The barrels can extend at an angle with respect to one another, and at least one of the barrels can have an

adjustable trajectory such that the barrel can pivot about a point on a longitudinal axis thereof. One or both barrels can also optionally be removably mated to the guide member.

In another embodiment, the device can include features to facilitate alignment of the 5 guide member with a spinal implant. By way of non-limiting example, the distal-most end of the elongate member can extend a distance beyond a distal-most end of the guide member to form an extension portion. The extension portion provides a surface that is preferably adapted to seat adjacent to a side-surface of a spinal implant mated to the guide member. The extension portion can also optionally or alternatively include a concave distal-most surface that is adapted to match the contour of a vertebral body, thereby facilitating alignment of the device with the vertebral 10 body. In yet another aspect of the invention, a distal end of the guide member or the elongate member can have at least one mating element formed thereon to mate with a corresponding mating element formed on a spinal implant. The mating element can be, for example a pin, spike, groove, cleat, hole, hook, threaded pin, threaded hole, and combinations thereof. In an exemplary embodiment, the mating element is effective to prevent rotation between the guide 15 member and the spinal implant when the devices are mated to one another.

In yet another embodiment of the present invention, a tissue retractor and guide kit is provided having at least two tissue retractor and guide devices. Each tissue retractor and guide device has an elongate member with a guide member mated thereto and including at least one barrel that defines a lumen for receiving a tool. In use, a distal portion of the elongate member is 20 adapted to retract tissue when the guide member is coupled to a spinal implant. In further aspects, the kit can include a cross member that is adapted to removably connect two tissue retractor and guide devices to one another. In an exemplary embodiment, the cross member is in the form of a generally rectangular housing that is adapted to fit around and retain a portion of the two elongate members. In another embodiment, the cross member can be an elongate rod 25 having opposed ends, each of which is adapted to removably mate to a tissue retractor and guide device.

In other aspects of the present invention, a spinal fixation kit is provided having a spinal fixation plate and at least one tissue retractor and guide device. The spinal fixation plate has a superior portion having at least one bore formed therein for receiving a fixation device that is

effective to mate the superior portion to a first vertebrae, and an inferior portion having at least one bore formed therein for receiving a fixation device that is effective to mate the inferior portion to a second, adjacent vertebrae. Each tissue retractor and guide device has an elongate member with a proximal handle portion and a distal, tissue-retracting portion, and a guide member mated to the distal portion of the elongate member. At least one lumen extends through the guide member for receiving a tool. In use, the guide member of the each tissue retractor and guide device is adapted to mate to a portion of the spinal fixation plate such that each lumen in the guide device is aligned with a bore in the fixation plate.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side perspective view of a tissue retractor and drill guide device according to one embodiment of the present invention;

FIG. 2 is a side view of the device shown in FIG. 1;

FIG. 3 is a top view of the device shown in FIG. 1;

FIG. 4 is an enlarged view of the distal portion of the device shown in FIG. 1;

FIG. 5 is a side view of the tissue retractor and drill guide device of FIG. 1 mated to one embodiment of a spinal fixation plate;

FIG. 6 is a perspective view of the device and the fixation plate shown in FIG. 5; and

FIG. 7 is a side view of two tissue retractor and drill guide devices mated to one another by a cross member, and mated to a spinal fixation plate according to another embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

As shown in FIGS. 1-4, the present invention provides a tissue retractor and guide device 10 that is useful during spinal surgery to retract tissue, as well as to facilitate implantation of a spinal implant, such as a spinal fixation plate. In general, the device 10 includes an elongate member 12 having a proximal, handle portion 14; and a distal portion 16 that is adapted to retract tissue disposed adjacent thereto. A guide member 30 is coupled to the distal portion 16 of the elongate member 12, and includes at least one lumen 32a, 32b extending therethrough for receiving a tool. In use, the guide member 30 is adapted to couple to a spinal implant and the distal portion 16 of the elongate member 12 is adapted to retract tissue disposed adjacent to the guide member 30. The device 10 is particularly advantageous in that it combines the functions of a tissue retractor and a drill guide, thereby allowing a surgeon to retract tissue surrounding a surgical site while simultaneously using the guide member 30 to introduce tools to facilitate implantation of a spinal implant. The device 10 further allows a relatively small incision to be used to access the surgical site since it eliminates the need for additional tissue retraction tools.

The device is also advantageous in that it allows a surgeon to selectively retract tissue only as needed, rather than retracting the tissue during the entire procedure, which can cause stress on the tissue.

A person skilled in the art will appreciate that, while the device 10 is described for use in connection with a spinal fixation plate, the tissue retractor and drill guide device can be used with a variety of implants for a variety of medical procedures.

The elongate member 12 of device 10 can have a variety of configurations, shapes and sizes, but it should be effective to retract tissue adjacent to the guide member 30 during use of the device 10. In an exemplary embodiment, the elongate member 12 has a proximal portion 14 that is adapted to extend out of a patient's body, and a distal portion 16 that is effective to retract tissue. The proximal and distal portions 14, 16 can be fixedly attached to, removably mated to, or integrally formed with one another, but preferably the proximal portion 14 is disposed at an angle β with respect to the distal portion 16 to facilitate visual access to the surgical site. While the angle β between the proximal and distal portions 14, 16 can vary, in an exemplary embodiment, the angle β is in the range of about 110° to 160° , and more preferably it is in the

range of about 125° to 145° . While only a single bend is shown between the proximal and distal portions 14, 16, a person skilled in the art will appreciate that the elongate member 12 can include two or more bends to facilitate visual access to the surgical site and/or to facilitate positioning of the device 10 in the patient's body. Moreover, the proximal portion 14 can 5 optionally be adjustably movable with respect to the distal portion 16 to allow the surgeon to adjust the angle and/or position of the proximal portion 14 with respect to the distal portion 16.

The proximal portion 14 of elongate member 12 can have a variety of configurations, but it preferably includes a handle 22 formed thereon or mated thereto. The handle 22 can have virtually any shape and size, and it can optionally include a gripping surface 24, such as a 10 knurled surface, ridges, or grooves, to further facilitate grasping of the device 10. In an alternative embodiment, or in addition to the handle 22, the proximal portion 14 of the elongate member 12 can include a clamp member (not shown) formed thereon or mated thereto that is effective to mate the device 10 to a surgical retractor, such as, for example a Bookwalter retractor. Alternatively, the surgical retractor can contain a post or surface for attaching to a 15 Bookwalter having a clamp. A person skilled in the art will appreciate that a variety of clamp members and/or other mating techniques can be used to mate the device 10 to a retractor or other type of support member.

The distal portion 16 of the elongate member 12 can also have a variety of shapes and sizes. In an exemplary embodiment, the distal portion 16 has a generally elongate shape and 20 includes front and back surfaces 16a, 16b that define a width W . The width W of the distal portion 16 can vary, but preferably the width W is sufficient to retract tissue around the guide member 30 to provide access to the guide member 30 and the surgical site. In an exemplary embodiment, at least a portion of the distal portion 16 has a width W that is equal to or greater than a width w of the guide member 30. The width W of the distal portion can also optionally increase in a proximal-to-distal direction. 25

As is further illustrated in FIG. 1, a distal-most end 40 of the distal portion 16 of the elongate member 12 can be adapted to facilitate placement of the device 10 at a surgical site. By way of non-limiting example, the distal-most end 40 of the device 10 can be adapted to rest against a vertebral body, and thus the distal-most end 40 can have a substantially concave shape.

to match the contour of a vertebra. A person skilled in the art will appreciate that the distal-most end 40 can have a variety of configurations, shapes and sizes, and it can be adapted to rest against a vertebra and/or against a spinal fixation plate.

As indicated above, the device further includes a guide member 30 formed on, mated to, or integrally formed with the distal portion 16 of the elongate member 12. The guide member 30 can have a variety of configurations, but it should include at least one lumen formed therein for receiving a tool, such as awl, a drill bit, a fastener, or a driver device. While the lumen(s) can be formed in a housing having virtually any shape and size, the guide member 30 preferably includes first and second lumens 32a, 32b formed therein. In an exemplary embodiment, the lumens 32a, 32b are formed through a solid block. For reference purposes, however, each lumen 32a, 32b will be described as being formed in a barrel 33a, 33b. A person skilled in the art will appreciate that the term "barrel" is not intended to be limited to substantially cylindrical members, but rather it can include a housing having virtually any shape and size. As shown in FIGS. 1-4, each barrel 33a, 33b includes a proximal end 35, a distal end 37, and an inner lumen 32a, 32b extending therebetween. The barrels 33a, 33b can be removably or fixedly mated to one another and/or to the guide member 30. In another embodiment, a base plate (not shown) can extend between the distal end 37 of each barrel 33a, 33b to mate the barrels 33a, 33b to one another and/or to the guide member 30. By way of non-limiting example, the base plate can include bores formed therein for removably or fixedly receiving the barrels 33a, 33b. Removable barrels 33a, 33b are particularly advantageous in that they allow barrels having different lengths to be selected based on the intended use.

In use, the distal end 37 of each barrel 33a, 33b, or a distal surface of the base plate, if provided, is adapted to rest against a spinal fixation plate. Thus, the distal end 37 of each barrel 33a, 33b and/or the distal surface of the base plate can have a shape that is adapted to match the contour of a spinal fixation plate. By way of non-limiting example, as shown in FIGS. 1 and 4, the distal end 37 of the barrels 33a, 33b can have a combined substantially concave shape that is adapted to rest against a spinal fixation plate having a convex surface. Each barrel 33a, 33b and/or base plate should, however, have a shape and size that results in the alignment of the lumens 32a, 32b in the barrels 33a, 33b with corresponding bores formed in a spinal fixation plate, being engaged by the device, as will be discussed below.

The position of each barrel 33a, 33b with respect to one another can also vary. As shown in FIG. 4, each barrel 33a, 33b can be positioned at an angle with respect to one another. More particularly longitudinal axes l_1 , l_2 of each barrel 33a, 33b can be positioned at an angle α_1 , α_2 with respect to a longitudinal axis L of the elongate member 12, such that the barrels 33a, 33b extend away from one another in a distal-to-proximal direction. The angles α_1 , α_2 are determinative of the entry angle of a tool or device being inserted through the lumens 32a, 32b in each barrel 33a, 33b, and thus the angles α_1 , α_2 should be set based on the intended use. While the angles α_1 , α_2 of the barrels 33a, 33b can vary, the barrels 33a, 33b preferably lie in a plane that is substantially parallel to at least a portion of a front surface 16a of the distal portion 16 of the elongate member 12. This is particularly advantageous in that it only requires a relatively small incision to be made in order to introduce the instrument into the surgical site, as the parallel guide member 30 reduces the size of the instrument compared to a device in which the guide member 30 is positioned at an angle with respect to the elongate member 12. In yet another embodiment, the angles α_1 , α_2 of one or both barrels 33a, 33b can be adjustable.

In use, the guide member 30 is preferably adapted to engage a spinal fixation plate such that the lumens 32a, 32b in the guide member 30 are aligned with corresponding bores formed in the spinal fixation plate. Accordingly, in order to facilitate alignment of the guide member 30 with the spinal fixation plate, the device 10 can include a variety of alignment features. In an exemplary embodiment, as shown in FIG. 5, the elongate member 12 can include an extension portion 28 that is adapted to be positioned adjacent to the side of the spinal plate 80 to provide a rough alignment between the device 10 and the spinal plate 80. The extension portion 28 is formed by attaching the guide member 30 to the distal portion 16 of the elongate member 12 at a position that is just proximal to the distal-most end 38 of the guide member 30. As a result, a portion of the elongate member 12, e.g., the extension portion 28, extends a distance beyond the distal-most end of the guide member 30. In use, the front surface of extension portion 28 can abut the side of a spinal plate 80 to align the guide member 30 with the plate 70. In addition to facilitating alignment, contact between the extension portion 28 and the spinal plate 80 can also prevent rotation between the device 10 and the spinal plate 80. While FIGS. 1-4 illustrate a substantially planar front surface 29, the front surface 29 of the extension portion 28 can optionally have a concave surface adapted to match the contour of an opposed convex surface on the spinal plate, thereby further aligning the device 10 with respect to the plate 80.

In another embodiment, the device 10 can include one or more mating elements formed on a portion thereof to mate the device 10 to a spinal fixation plate. By way of non-limiting example, FIG. 4 illustrates one embodiment of a mating element in the form of a protrusion or pin member 42 that extends from a distal surface 38 of the guide member 30 at a location that is substantially between the first and second barrels 33a, 33b. The pin member 42 is adapted to extend into corresponding detents or bores formed in a spinal fixation plate, such as, for example, spinal plate 80 shown in FIG. 5. The pin member 42 can optionally extend at an angle to further facilitate grasping the spinal plate 80. In an exemplary embodiment, the mating element 42 is adapted to prevent rotation between the guide member 30 and the spinal plate 80 to provide stability to the connection. By way of non-limiting example, mating elements with non-symmetrical shapes, such as a pin with a non-circular cross section (e.g. rectangular, oval, triangular, irregular), a multi-pronged mating element, or a tongue and groove combination, can prevent or reduce the tendency of the device 10 to pivot with respect to the spinal plate 80.

A person skilled in the art will appreciate that a variety of techniques can be used to mate the device 10 to the spinal plate 80, and that the mating element 42 can be formed on any portion of the device 10 and it can be adapted to grasp any portion of the spinal plate 80. By way of non-limiting example, other suitable mating techniques include a snap-fit engagement, an interference fit, a spring clip, a threaded engagement, and any other mechanical connection.

FIGS. 5 and 6 illustrate the device 10 mated to an exemplary embodiment of a spinal fixation plate 80. In general, the spinal plate 80 includes a superior and an inferior portion 81, 83, each having at least one bore 82 formed therein for receiving a fixation device, e.g., a screw, to mate the plate 80 to a vertebra. The inferior and superior portions 81, 83 can optionally be slidably movable with respect to one another such that the height of the plate 80 is adjustable. In use, the plate 80 is adapted to span across two vertebra such that the proximal portion 81 is mated to one vertebra and the distal portion 83 is mated to an adjacent vertebra. As indicated above, the device 10 can be mated to one of the inferior or superior portions 81, 83 of the spinal plate 80 by first positioning the extension portion 28 adjacent to a side on one of the inferior and superior portions 81, 83 of the spinal plate 80 to provide a rough alignment. The handle 22 on the elongate member can then be manipulated to insert the mating element, e.g., pin 42, on the guide member 30 into the corresponding receiving-bore (not shown) formed in the spinal plate

80. In this configuration, the lumens 32a, 32b of guide member 30 are aligned with the bores 82 formed in the spinal plate 80.

With the distal portion of device 10 mated to and aligned with the spinal plate 80, the handle 22 can be used to retract tissue around the implant site, and to position the plate against adjacent vertebrae. The handle can then either be held in position, or attached to an external support structure, such as a Bookwalter, using a clamp disposed on the handle or on the external support, to maintain the position of the spinal plate against the vertebrae.

When the plate is properly positioned against the spine and the tissue retractor and drill guide 10 is aligned with the plate, a tool, such as a drill, awl, tap, or implant, can be passed through the each lumen 32a, 32b in the guide member 30 to form a borehole in the vertebrae and/or to insert a spinal implant into the vertebrae.

In another embodiment, as shown in FIG. 7, two tissue retractor and guide devices can be mated to a single spinal plate 80 to retract tissue disposed around the entire plate 80, and to allow a surgeon to efficiently prepare the vertebrae and implant the plate 80. As shown, a first tissue retractor and guide device 10a is mated to a inferior portion 81 of the spinal plate 80, and a second tissue retractor and guide device 10b is mated to the superior portion 83 of the spinal plate 80. Where the plate 80 has an adjustable height, as previously discussed, the guide devices 10a, 10b are preferably used to fully extend the plate 80. In order to maintain the position of the two devices 10a, 10b with respect to one another, the present invention also provides a cross member 50 that is removably matable to the two devices 10a, 10b. In an exemplary embodiment, two tissue retractor and guide devices 10a, 10b and a cross member 50 are provided in a kit.

The cross member 50 can have a variety of configurations, and in one embodiment (not shown), it can include an elongate rod having opposed ends. Each end is preferably adapted to removably mate to a tissue retractor and guide device 10a, 10b. In another embodiment, as shown in FIG. 7 the cross member 50 is in the form of a substantially rectangular-shaped housing that is adapted to fit around the elongate member 12a, 12b of each device 10a, 10b. The rectangular shape of the cross member 50 is particularly advantageous in that it provides a window to the surgical site, thereby allowing the surgeon to access the guide member 30a, 30b

on each device 10a, 10b. A person skilled in the art will appreciate that the cross member 50 can have virtually any shape and size including, but not limited to, oval, rectangular, circular, and irregular.

The device can be formed from a variety of materials, including metals, such as stainless steel, and plastics. In an exemplary embodiment, however, the device, or at least a portion of the device, is formed from a radio lucent material to facilitate intraoperative imaging of the surgical site. By way of non-limiting example, suitable radio lucent materials include carbon fiber, radel, or any other biocompatible plastic or other material.

One of ordinary skill in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is: